

The Office Action refers to several passages within Arminjon *et al.* in support of this rejection. Specifically, it points to Example 1 of Arminjon *et al.* for

Arminjon *et al.* disclose the identical vaccine and method instantly claimed. The vaccine for young children comprises pertussis toxoid and filamentous hemagglutinin in purified form, tetanus toxoid, diphtheria toxoid, inactivated polio virus, a conjugate of a carrier molecule selected from tetanus toxoid and diphtheria toxoid and capsular polysaccharide of *H. influenza* type B (HiB) and an aluminum salt, see example 1 of AU 708777.

In fact, however, Arminjon *et al.* Example 1

- discloses a pertussis cell mixture, not a pertussis toxoid in purified form as recited in the present claims;
- does not disclose inactivated poliovirus as a component as recited in the present claims;
- does not disclose filamentous hemagglutinin in purified form as recited in the present claims.

The Office Action also refers to pages 2-4 of Arminjon *et al.* for teachings regarding adsorbing tetanus and diphtheria toxoids onto an aluminum salt before mixing with other components as well as preparing the conjugate in a phosphate buffer before being mixed with other components. But Arminjon teaches nothing of the sort. With regard to the method of making the Arminjon *et al.* vaccine, Arminjon *et al.* teaches at p. 3, ln. 32 *et seq.*:

The invention likewise relates to a method of manufacture of a vaccine composition comprising at least one antigen formed by the capsular polysaccharide of *Haemophilus influenzae* type b or high molecular weight polyribosylribitol phosphate coupled to tetanus anatoxin, **characterized in that it consists in adding an adjuvant to the vaccine composition by means of a suspension of aluminum complexes having a point of zero charge of less than approximately 7.2.**

Emphasis added. This is not a teaching or suggestion to adsorb the tetanus and diphtheria toxoids onto a aluminum salt before mixing with other components or to prepare the conjugate in phosphate buffer before mixing with the other components, both as presently claimed. Nor are there any other teachings or suggestion in this regard on pages 2-4 of Arminjon *et al.* or anywhere else.

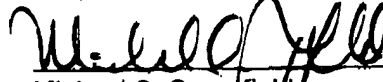
In summary, Arminjon *et al.* fails to teach or suggest all of the limitations of the present claims and, therefore, can neither anticipate the invention of the present claims nor render it obvious. In view of

all of the foregoing, the applicants respectfully request reconsideration and withdrawal of this § 102/103 rejection.

If there are any questions or comments regarding this Response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

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Respectfully submitted,


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U.S. APPLICATION 09/508,570**Redline d Version of Amended Claims**

21. (Twice Amended) A method for preparing a stabilized multi-component vaccine, the method comprising mixing at least:

- a) pertussis toxoid and filamentous hemagglutinin in purified form,
- b) tetanus toxoid,
- c) diphtheria toxoid,
- d) inactivated polio virus,
- e) a conjugate of a carrier molecule selected from tetanus toxoid and diphtheria toxoid and a capsular polysaccharide of *Haemophilus influenzae* type B, and
- f) an aluminum salt,

wherein tetanus toxoid and diphtheria toxoid are adsorbed onto the aluminum salt before being mixed with the other components and the conjugate is prepared in a phosphate buffer solution before being mixed with the other components.

36. (Twice Amended) A method for conferring protection in a host against disease caused by *Bordetella pertussis*, *Clostridium tetanii*, *Corynebacterium diphtheriae*, *Haemophilus influenzae*, *Poliovirus* and/or *Hepatitis B virus* using comprising administering an effective amount of a multi-component vaccine obtained by the method of claim 27.

37. (Twice Amended) A method of immunizing a human host against disease caused by infection by *Bordetella pertussis*, *Clostridium tetanii*, *Corynebacterium diphtheriae*, *Haemophilus influenzae*, *Poliovirus*, and/or *Hepatitis B virus*, which method comprises administering to the host an effective amount of a multi-component vaccine obtained by the method of claim 27.